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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,711	04/17/2001	Stephen G. Withers	UBC. P-005 - 2	1131

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EXAMINER	
SLOBODYANSKY, ELIZABETH	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/837,711	WITHERS ET AL.	
	Examiner	Art Unit	
	Elizabeth Slobodyansky, PhD	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *71-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *71-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/21/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed March 21, 2005 canceling claims 40-50 and 55 and adding claims 71-83 has been entered.

Claims 71-83 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 71-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for synthesizing a glycoside product by coupling a glycosyl donor molecule and a glycoside acceptor molecule using a mutant form of glycosidase enzyme, said enzyme being selected from among glycosidase enzymes having two catalytically active amino acids with carboxylic acid side chains within the active site of the glycosidase, said mutant enzyme being mutated to replace one of said catalytically active amino acids having a carboxylic acid side chain with a different amino acid of smaller size. Claims are further limited to retaining and inverting glycosidases (claim 72, with dependent claims 73-76, and claim 81, respectively).

Therefore, the claims are drawn to a method of use of the genus of mutant glycosidases. Said genus encompasses not only naturally occurring but also man made structures that are structurally limited only by the presence of two catalytically active carboxylic residues. The genus of glycosidases encompasses enzymes with different structures, functions and catalytic mechanisms, i.e. retaining and inverting. It comprises, in addition to the subgenus of naturally occurring glycosidases, numerous structural variants of naturally occurring glycosidases, the structures of which are defined only by two catalytic carboxylic amino acids. The specification teaches three representative species, all three retaining enzymes, including Abg (β-1, 4 glucosidase from *Agrobacterium faecalis*) that is mutated at the active site nucleophile Glu358Ala, mutant α-amylase (human or porcine) where Asp197 is mutated and yeast α-glucosidase where Asp216 is mutated (page 11, lines 1-7). Three representative species, all the wild type glycosidases, are insufficient to represent a highly diverse genus of glycosidases because a significant number of structural differences between the genus members is permitted.

Given this lack of description of representative species encompassed by the genus of glycosidases comprising both naturally occurring and man made enzymes, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Amending the claims to recite "wild type glycosidase" instead of "glycosidase", for example, would obviate this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 71-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 71, with dependent claims 72-83, recites on one hand synthesis of "a glycoside product" and on the other hand "the hydrolysis of the oligosaccharide and retains the activity to synthesize the oligosaccharide" and "to synthesize the glycosyl glycoside product" (emphasis added). The metes and bounds of the claim are unclear because "glycoside product" is not necessarily an "oligosaccharide" and the term "the glycosyl glycoside product" does not have an antecedent basis.

Furthermore, claim 71 recites "good leaving group". It is unclear which properties render the group "good". Claim 71 recites donor and acceptor "corresponding to the glycosidase enzyme and to the glycoside product to be synthesized". Because the different type of relationships exists between the enzyme and its substrate and between the substrate and the product, clearer wording is suggested. For example, donor and acceptor "corresponding to the glycosidic bond hydrolyzed in the substrate by the wild type glycosidase".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321□ may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 71-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,716,812. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: a method of coupling a glycosyl donor and a glycoside acceptor having opposite stereochemical configurations using a mutant glycosidase.

Claims 71-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,284,494. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: a method of coupling a glycosyl donor and a glycoside acceptor having opposite stereochemical configurations using the *Agrobacterium* β-glucosidase E358A mutant as defined in claims 1 and 2 of U.S. Patent No. 6,284,494.

Applicant's consideration for filing a TD stated in Responses filed June 3, 2002, March 4, 2003, November 24, 2003, August 30, 2004 and the current Remarks (page 11) is noted. The rejections are maintained until TD is filed.

Response to Arguments

Applicants' arguments filed on March 21, 2005 have been fully considered but they are not persuasive.

With regard to the 112, 1st paragraph, written description rejection, its remaining part related to the genus of glycosidases is explained in detail above.

The enablement rejection is moot in view of cancellation of claims 40-50, 55.

The previous 112, 2nd paragraph rejection is moot in view of cancellation of claims 40-50, 55. The current 112, 2nd paragraph rejection of claims 71-83 is explained in detail above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner
Art Unit 1652

July 8, 2005